



Food and Drug Administration  
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April 24, 2015

Codent Technical Industry Co., Ltd.  
Mr. Wen Chin-Ting  
Specialist  
5F, No. 90 Luke 5<sup>th</sup> Road  
Luzhu District, Kaohsiung City 82151  
TAIWAN

Re: K150798  
Trade/Device Name: Codent Low Speed Dental Handpieces and Accessories  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental Handpiece and Accessories  
Regulatory Class: I  
Product Codes: EFB, EGS  
Dated: March 16, 2015  
Received: March 26, 2015

Dear Mr. Chin-Ting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Section 6

### **Indications for Use Statement**

**Indications for Use Statement**

**510(k) Number** K150798  
(if know)

**Device Name** Codent Low Speed Dental Handpieces and Accessories

**Indications for Use** Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Section 7

### **510(k) Summary**

## **510(k) Summary**

### **7-1 Submission Date:**

Apr 02, 2015.

### **7-2 Type of 510(k) Submission:**

Special 510(k) K150798

### **7-3 Submitter Address and Registration:**

<b>Manufacturer:</b>	Codent Technical Industry Co., Ltd
<b>Address:</b>	5F., No.90, Luke 5th Rd., Luzhu Dist., Kaohsiung City 821, Southern Taiwan Science Park, Taiwan
<b>Phone:</b>	+886-7-695-5533 ext.812
<b>Fax:</b>	+886-7-695-5683
<b>Contact:</b>	Chin-Ting Wen / Specialist
<b>Establishment Registration Number:</b> 3004082152	

### **7-4 Identification of the Device:**

<b>Device Trade Name</b>	Codent Low Speed Dental Handpieces and Accessories
<b>Common Name:</b>	Air-Powered Dental Handpieces & Contra- And Straight-Angle Attachment
<b>Classification Name</b>	Dental Handpiece & Accessories
<b>Device Classification</b>	1
<b>Regulation Number</b>	872.4200
<b>Panel</b>	Dental
<b>Product Code</b>	EFB/EGS

### **7-5 Predicate Device Information:**

<b>Predicate Device Name:</b>	Codent Low Speed Dental Handpieces and Accessories
<b>Manufacturer:</b>	Codent Technical Industry Co., Ltd.
<b>Product Code:</b>	EFB/EGS
<b>510(k) Number:</b>	K133069
<b>Concurrence date</b>	October 24, 2014

## **7-6 Intended Use and Indications for Use of the Subject Device:**

Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

## **7-7 Device Description and Comparison with Predicate Device:**

### **7-7-1 Device Description**

Codent Low Speed Dental Handpieces and Accessories include low speed air motor, straight handpiece and contra-angle handpiece. The device description of the Codent Low Speed Dental Handpieces and Accessories is as follows.

- The gear ratios of handpieces are 1:5 and 1:1
- The handpieces have maximum speed of 200,000 rpm and minimum speed of 40,000 rpm.
- The air motors are capable of running up to a speed of 25,000 rpm.
- AI6C and AI2C air motors can be connected to LEIPB1, LEIPA1, A11, A65L, A65, A61L and A61 handpieces; LAISA1, LBIPA1, LEIPD4 and LEIPC4 of Codent's FDA 510(k) K133069.
- E-1110 and E-1100 air motors can be connected to E-2000, E-4010 and E-4000 handpieces.

### **7-7-2 The Modification of the Subject Device**

The only modifications that were made are:

- Adding new models of Codent Low Speed Handpiece that the shaft materials of Codent Low Speed Dental Handpieces are different from the shaft materials of the K133069, but the same materials of the sleeve materials of K133069.
- Adding new models for market segment that are not change any of the design of Codent Low Speed Dental Handpieces and accessories of K133069.
- Adding a new model that has LED light function in Air Motor, the accessories of Codent Low Speed Dental Handpieces.
- Adding a new model that only has 2 holes of Air Motor, the accessories of Codent Low Speed Dental Handpieces, to comply with 2 holes dental unit needed.

**7-7-1 The same and the different technological characteristics comparison with Predicate Device K133069**

The same and the different technological characteristics comparison with Predicate Device K133069 as follows:

➤ **Subject Device (Model: A11) comparison with Predicate Device LAISA1 and LDEPA2:**

– The same technological characteristics:

- The Subject Device, Model: A11 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LAISA1.
- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of A11 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.

– The difference technological characteristics:

- The only difference is device design between the Subject Device, Model: A11 and Predicate Device, Model: LAISA1 that the materials used in Shaft. The Shaft materials of A11 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LAISA1 is Stainless Steel (Coating Materials: None / Coating Range: Parts Appearance).

➤ **Subject Device (Model: E-2000) comparison with Predicate Device LAISA1 and LDEPA2:**

– The same technological characteristics:

- The Subject Device, Model: E-2000 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in

rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LAISA1.

- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of E-2000 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.

- The difference technological characteristics:

- The only difference between the Subject Device, Model: E-2000 and Predicate Device, Model: LAISA1 is the device design that the materials used in Shaft. The Shaft materials of E-2000 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LAISA1 is Stainless Steel (Coating Materials: None / Coating Range: Parts Appearance).

➤ **Subject Device (Model: A61L) comparison with Predicate Device LBIPA1 and LDEPA2**

- The same technological characteristics:

- The Subject Device, Model: A61L has the same intended use, device design (Operational modes, Cooling System, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LBIPA1.
- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of A61L are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.
- The device design of the A61L is the same as the Predicate Device, Model: LEIPD4.

- The difference technological characteristics:

- The difference device design between the Subject Device, Model: A61L and Predicate Device, Model: LBIPA1 are the materials used in Shaft and Fiber optics Light Function. The Shaft materials of A61L is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but

LBIPA1 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance). And the A61L has the Fiber optics Light Function but LBIPA1 hasn't.

➤ **Subject Device (Model: A61) comparison with Predicate Device LBIPA1 and LDEPA2:**

➤ The same technological characteristics:

- The Subject Device, Model: A61 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LBIPA1.
- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of A61 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.

- The difference technological characteristics:

- But the only difference in the device design between Subject Device, Model: A61 and Predicate Device, Model: LBIPA1 is the materials used in Shaft. The Shaft materials of A61 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LBIPA1 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).

➤ **Subject Device (Model: A65L) comparison with Predicate Device LEIPD4 and LDEPA2:**

➤ The same technological characteristics:

- The Subject Device, Model: A65L has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in

rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LEIPD4.

- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of A65L are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.

- The difference technological characteristics:

- The only different device design between Subject Device, Model: A65L and Predicate Device, Model: LEIPD4 is the materials used in Shaft. The Shaft materials of A65L is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LEIPD4 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).

➤ **Subject Device (Model: A65) comparison with Predicate Device LEIPC4 and LDEPA2:**

➤ The same technological characteristics:

- The Subject Device, Model: A65 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LEIPC4.

- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of A65 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.

- The difference technological characteristics:

- The only different device design between the Subject Device, Model: A65 and Predicate Device, Model: LEIPC4 is the materials used in Shaft. The Shaft materials of A65 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LEIPC4 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).

- **Subject Device (Model: E-4010) comparison with Predicate Device LBIPA1, LBIPA1 and LEIPD4:**
- The same technological characteristics:
  - The Subject Device, Model: E-4010 has the same intended use, device design (Operational modes, Cooling System, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LBIPA1.
  - In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of E-4010 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.
- The difference technological characteristics:
  - The Shaft materials of Subject Device, Model: E-4010 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but Predicate Device, Model: LBIPA1 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).
  - Subject Device, Model: E-4010 also has light function (fiber optics) that Predicate Device, Model: LBIPA1 hasn't, but in comparison to the other Predicate Device Models, Model: LEIPD4, the device design of light function is the same as LEIPD4. The light function could make dentists see clearly in oral treatment working place.
- **Subject Device (Model: E-4000) comparison with Predicate Device LBIPA1 and LDEPA2:**
- The same technological characteristics:
  - The Subject Device, Model: E-4000 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LBIPA1.

- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of E-4000 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.
- The difference technological characteristics:
  - The only different device design between the Subject Device, Model: E-4000 and Predicate Device, Model: LBIPA1 is the materials used in Shaft. The Shaft materials of E-4000 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LBIPA1 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).
- **Subject Device (Model: LEIPB1) comparison with Predicate Device LBIPA1 and LEIPD4:**
- The same technological characteristics:
  - The Subject Device, Model: LEIPB1 has the same intended use, device design (Operational modes, Cooling System, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LBIPA1.
  - In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of LEIPB1 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.
- The difference technological characteristics:
  - The only different device design between the Subject Device, Model: LEIPB1 and Predicate Device, Model: LBIPA1 is the materials used in Shaft. The Shaft materials of LEIPB1 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LBIPA1 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).
  - Subject Device, Model: LEIPB1 also has light function (fiber optics) that Predicate Device, Model: LBIPA1 hasn't, but in comparison to the other Predicate Device Models, Model: LEIPD4, the device design of light function is the same as LEIPD4. The light function could make dentists see clearly in oral

treatment working place.

➤ **Subject Device (Model: LEIPA1) comparison with Predicate Device LBIPA1 and LDEPA2:**

- The same technological characteristics:

- The Subject Device, Model: LEIPA1 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: LBIPA1.
- In comparison to other Predicate Device Models, Model: LDEPA2, the Shaft materials of LEIPA1 are the same as the materials that LDEPA2 used in Sleeve that sleeve and shaft are the same as the hand-held parts of handpieces.

- The difference technological characteristics:

- The only different device design between the Subject Device, Model: LEIPA1 and Predicate Device, Model: LBIPA1 is the materials used in Shaft. The Shaft materials of LEIPA1 is Aluminum (Coating Materials: Aluminum (Anodizing) / Coating Range: Parts Appearance), but LBIPA1 is Brass (Coating Materials: Titanium / Coating Range: Parts Appearance).

➤ **Subject Device (Model: AI6C) comparison with Predicate Device AI4C:**

- The same technological characteristics:

- The Subject Device, Model: AI6C has the same intended use, device design (Operational modes, Cooling System, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: AI4C.

- The difference technological characteristics:

- The only one different device design between Subject Device, Model: AI6C and Predicate Device, Model: AI4C is the adding light function (fiber optics) of AI6C. The light function could make dentists see clearly in oral treatment working place.
  
- **Subject Device (Model: AI2C) comparison with Predicate Device AI4C and AI2N:**
  - The same technological characteristics:
    - The Subject Device, Model: AI2C has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: AI4C.
    - The hose connector's dimension of Subject Device, Model: AI2C is the same as the Predicate Device, Model: AI2N.
  - The difference technological characteristics:
    - The hose connector's dimension is different. The Subject Device, Model: AI2C is two holes design and the Predicate Device, Model: AI4C is four holes design. The choice of the holes of Air Motors are according to the dental units' hose connectors design and are not change the substantive functionality and safety in handpiece and air motor.
  
- **Subject Device (Model: E-1110) comparison with Predicate Device AI4C:**
  
- The same technological characteristics:
  - The Subject Device, Model: E-1110 has the same intended use, device design (Operational modes, Cooling System, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Lubricant, Gear ratio are the same) as the Predicate Device, Model: AI4C.

- The difference technological characteristics:
  - The only different device design place between the Subject Device, Model: E-1110 and Predicate Device, Model: AI4C is the adding light function (fiber optics) of E-1110. The light function could make dentists see clearly in oral treatment working place.
- **Subject Device (Model: E-1100) comparison with Predicate Device**
- The same technological characteristics:
  - The Subject Device, Model: E-1100 has the same intended use, device design (Operational modes, Cooling System, Fiber optics, Dimensions, Type of chuck, Coupling dimensions, Accessories are the same) and technical specifications (Light intensity, Bur extraction force, Maximum air/water pressure, Speed in rpms, Bur Size, Lubricant, Gear ratio are the same) as the Predicate Device, Model: AI4C. This adding new model is for market segment purpose.
- The difference technological characteristics:
  - None.

### **7-8 Substantial Equivalent Devices :**

The modified Codent Low Speed Dental Handpieces and Accessories have the following similarities to those which previous received 510(k) concurrence:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic Codent Low Speed Dental Handpieces and Accessories design,
- head of the Codent Low Speed Dental Handpieces incorporate the same materials,
- sleeve of the Codent Low Speed Dental Handpieces incorporate the same materials,
- shaft of the Codent Low Speed Dental Handpiece incorporate the same materials of Sleeve of the Codent Low Speed Dental Handpieces,
- air Motor, the accessories of Low Speed Dental Handpieces, incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

More comparative items are listed in Section of Substantial Equivalence Discussion, the tables and charts substantiate CODENT TECHNICAL INDUSTRY Co., Ltd's claim of the existence of predicate devices.

<b>Intended Use</b>	
Proposed Device	Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. The intended use is the same as in K133069.
Predicate Device (K133069)	Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.
<b>Models</b>	
Proposed Device	LEIPB1, LEIPA1, A61L, A61, A65L, A65, A11, E-2000, E-4010, E-4000, AI6C, AI2C, E-1110, E-1100.
Predicate Device (K133069)	LAISA1, LBIPA1, AI4C, AI2N, LAESA2, LDEPA2, AE4N, AE2N, LEIPD4, LEIPC4.

## **7-9 Non-Clinical Testing**

### **7-9-1 Modify the Shaft materials of the Subject Device from Brass to Aluminum, but the Aluminum materials are used in the Sleeve of handpiece in Predicate Device**

The Codent Low Speed Dental Handpieces and Accessories (K150798) use the same materials of Codent Low Speed Dental Handpieces and Accessories (K133069). We change of the Shaft materials of the Subject Device from Brass to Aluminum that are used in the Sleeve of handpiece in Predicate Device. Because the Aluminum could change the appearance color according to anodized process. The Aluminum are used in the Sleeve of handpiece in Predicate Device which means there is no any concern regarding biocompatibility.

#### **Risk assessment:**

The materials of Codent Low Speed Dental Handpieces and Accessories (K150798) is the

same as the Predicate Device, K133069. There is no any concern regarding biocompatibility risk.

### **7-9-2 Adding LED light function in Handpiece and Air Motor.**

The fiber optic glass rod of Codent's dental handpiece is set a hard-clad fiber in handpiece's internal, and the hard-clad fiber is coated quartz glass fiber and made by high temperature vacuum sintering. Such production methods can make the lighting system smaller and avoid the fiber swing condition. The end of fiber optic glass rod in handpiece is connected to the LED lamp or halogen lamp light source of AI6C and E-1110, and the light source of AI6C and E-1110 projected light conducted by total internal reflection. Visible light can be efficiently transmitted through optical fibers and routed around corners and into inaccessible areas for lighting applications. Light emitted from the head of handpiece section which used in dental treatment. The fiber optic glass rod is located inside the handpiece and the design must consider the remaining space and angle of handpiece.

AI6C and E-1110 has two light sources, one is LED lamp and the other is Halogen lamp. The LED light source of AI6C and E-1110 is projected onto the end of handpiece, light source conduct through the fiber optic glass rod, then the head of handpiece reveal bright. And the light intensity of Codent's handpiece is at 27,000 lux maximum with LED lamp Air Motor and 20,000 lux maximum with halogen lamp Air Motor.

#### **Risk assessment:**

The LED lamp voltage is DC 3.8V, and the electric current is 20mA. The Halogen lamp voltage is DC 3.5V, and the electric current is 740mA that are a very small amount that does not cause high temperature risk.

### **7-9-3 Adding 2 holes design of Air Motor to comply with 2 holes dental unit needed.**

The Subject Device, Model: AI2C hose connector's dimension is 2 holes design (drive air hole and spray water hole), but Predicate Device AI4C (K133069) hose connector's dimension is 4 holes design (drive air hole, exhaust air hole, spray air hole and spray water hole). In 2 holes design, the air comes from dental unit through the drive air hole of air motor into the head of handpiece, and dispersed two kinds of gas pipeline, one is for operating the turbine-driven and the other is to produce spray air to cause cooling mist. The remaining gas will be exhausted through the bottom of the handpiece. In 4 holes design, the drive air and spray air are dispersed two kinds of gas pipeline in air motor directly, and the

remaining gas will be exhausted through the exhaust air hole of air motor into dental unit pipeline.

**Risk assessment:**

*The dental unit has two holes or four holes connector design, and the purpose of operating the turbine-driven, produce spray air to cause cooling mist and exhaust the remaining gas are the same. The difference is only the pipeline route design, so there are not change the functionality and performance in handpiece and air motor. The change would not cause additional risk.*

**7-9-4 Functionality and Performance Test Results**

We execute the bench testing about drop, noise, air supply, spray air supply, water supply, air and water pressure stability, temperature, vibrations, resistance to reprocessing, operating control, usability, chuck system for shanks, speed, eccentricity, torque and the experiment of illumination of the handpiece and air motor to detect whether the changes of design will cause any actual performance impact or not.

**Risk assessment:**

*And the changes of design don't affect the functionality and performance test results that would not cause additional risk.*

**7-10 Conclusion:**

After the risk assessment and analysis of performance bench testing data, it can be concluded that Codent Low Speed Dental Handpieces and Accessories is substantially equivalent to the predicate devices.